**Amgen Inc., v. Chugai Pharmaceutical Co., Ltd., and Genetics Institute, Inc.**

(U.S. Court of Appeals for the Federal Circuit - 927 F.2d 1200 (Fed. Cir. 1991))

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## Summary

In the U.S. case of *Amgen, Inc. Vs. Chugai Pharmaceutical*, the Court of Appeals for the Federal Circuit (hereinafter: the Court) held that for the patenting of microorganisms the best mode disclosure requirement does not necessarily entail an obligation by the patent applicant to deposit a sample of the claimed microorganism.


## The Facts

The case arose as a result of a race between two leading biotechnology companies to clone the gene for the human hormone erythropoietin (EPO). EPO is useful in treating anemia in kidney dialysis patients. The two companies Amgen and Genetics Institute (GI) each held a patent related to recombinant erythropoietin technology (rEPO), a new technique for producing EPO. GI licensed its patent rights to Chugai Pharmaceuticals for the Japanese market and to a cooperative venture between Chugai and Upjohn Company for the U.S. market. Amgen filed a suit against GI and its licensee, Chugai.

Amgen alleged that GI and Chugai infringed its patent (the '008 patent) by the production and use of rEPO, and that Chugai, as a result of a collaborative relationship with GI, had induced and contributed to the direct infringement of the '008 patent by GI. Amgen further sought that Chungai's future activities in the production and sale of rEPO would infringe the Amgen '008 patent.

GI and Chungai counterclaimed, asserting several affirmative defenses, including that the '008 patent would have enabled skilled scientists to make a host cell yielding some degree of EPO production, but not the best mode. They argued that the failure to make deposits at a public depository of biological materials allegedly necessary for enabling the best mode of practicing the invention did not meet the best mode requirement under 35 U.S.C § 112. In their view the Amgen patent was therefore unenforceable.

Amgen argued that the patent adequately described the best mode of the invention. A record indicated that the best mode host cell was disclosed in an example called "Example 10". Example 10 described expression systems employing CHO DHFR[1] cells, which were publicly available. In a testimony before the district court Dr. Simonsen, GI's own expert, indicated that

[1] The district court found that the "best mode" of practicing the claimed invention was by use of a specific genetically-heterogenous strain of Chinese hamster ovary (CHO) cells, which produced EPO at a rate greater than that of other cells.

by following Example 10, one skilled in the art could eventually reproduce or generate cell lines making some level of EPO.

The district court relied on Dr. Simonsen's testimony and found that the best mode of practicing the claimed invention was by the use of CHO, which was disclosed in Example 10. It held that one skilled in the art could not duplicate the best mode without having first deposited a sample of the specific cells found in Example 10. The Court agreed with the district court's determination that the invention had been sufficiently disclosed and ruled that GI had infringed the '008 patent.

**The Legal Issues**

The main question before the Court was whether for the patenting of microorganisms the best mode requirement may only be met by a deposit of the claimed microorganism.

GI and Chugai argued that in the field of living materials a biological deposit should be required so that the public has access to exactly what the patent applicant contemplates as the best mode.

The Court declined to hold that the only way to meet the best mode requirement for a transfected host cell was to make a deposit where the best mode of preparing a cell line necessary to practice the invention was disclosed and enabled in the specification. It further held: *"The testimony is clear that no scientist could ever duplicate exactly the best mode used by Amgen, but that those of ordinary skill in the art could produce mammalian host cell strains or lines with similar levels of production."*[2]

The Court further noted that the defendants did not show clearly and convincingly that the best mode requirement of § 112 was not met. The Court stated: *"Where an invention depends on the use of living materials ... it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of written disclosure."*[3]

According to the Court, the defendants should have provided evidence that in the present case, written disclosure alone would not enable the public to make the invention, but that a deposit was necessary.

The Court ruled: *"It is well established that a patent applicant is entitled to claim his invention generically, when he describes it sufficiently to meet the requirements of Section 112. A specification may, within the meaning of 35 U.S.C. Sec. 112 p 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses."*[4]

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[2] See id. at 1212

[3] See id. at.1210, citing this Court's decision in: *Lundak, 773 F.2d 1216, 1220, 227 USPQ 90, 93 (Fed.Cir.1985)*

[4] See the decision of the Court in: *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed.Cir.) , p. 1206*

The Court found that GI had infringed Amgen's patent and barred it from marketing rEPO in the United States. This decision ensured that only Amgen's version of rEPO would be available in the United States for the duration of its patent protection.

**Points of significance**

- In the United States the best mode requirement (see case summary of *Spectra Physics v. Coherent*, available in this database) may require the deposit of biological material.
- A biological deposit may be necessary where biological material is required to practice an invention and "*words alone cannot sufficiently describe how to make and use the invention in a reproducible manner*."[5]
- If *"words alone cannot sufficiently describe"* the invention such that a biological deposit would normally be required, such a deposit would still not be necessary if the biological material necessary to the invention is (1) known and readily available to the public or (2) derived from readily available starting materials through routine screening that does not require undue experimentation.[6]
- The TRIPS Agreement (Art. 29) is silent on the issue of depositing microorganisms to meet the best mode requirement. WTO members are free to design their national provisions in that respect.

**Key words:** *Pre-grant flexibilities, Patent, Patentability, Best Mode Requirement, Enablement Requirement, Person Skilled in the Art, Deposit of Microorganisms, Biological Material.*

**Available at:** https://law.justia.com/cases/federal/appellate-courts/F2/927/1200/109675/

[5] Manual of Patent Examining Procedure: MPEP § 2402
[6] See id. at 1210, citing this Court's decision in: *Wands, 858 F.2d 731, 735-36, 8 USPQ2d 1400, 1403 (Fed.Cir.1988)*